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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 10/785,665 | 02/23/2004 | Timothy A. Ringeisen | KN P 0142 | 2680 |
| 42016 | 7590 | 12/12/2007 | | |
| KENSEY NASH CORPORATION 735 PENNSYLVANIA DRIVE EXTON, PA 19341 | | | EXAMINER AZPURU, CARLOS A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 12/12/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/785,665 | Applicant(s) RINGEISEN ET AL. | |
| | Examiner Carlos A. Azpuru | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09/27/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 12-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>04028904&12222005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the information disclosure statements filed 04/02/2004 and 12/22/2005.

Election/Restrictions

Applicant's election without traverse of Group I, species 1, claims 1-11, in the reply filed on 09/27/2007 is acknowledged.

Applicant's comments concerning rejoinder have been noted. However, none of the other generic claims is generic to this embodiment.

Claims 12-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/27/2007.

Claim Objections

Claims 2-5 and 7-8 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 3-5 fail to further limit claim 1 because claim 1 has already set out that the bioactive is part of the implantable gel. Whether it is in the solvating fluid or dried gel is not important unless applicant were claiming a method. As such, the composition itself is not further limited.

The same applies to claims 7-8. These claims should depend from claim 6, however, they do not set any new limitations out since as explained about claim 6 already sets out a further comprising step which adds filler to the implantable gel.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 5 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-11 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Delmotte (US Patent No. 6,599,515).

Delmotte disclose mixing the dry gel material with fluid (see Abstract; col 15, lines 25-32). Filler material is added in the form of calcium containing bone-like material at col. 5, line 60-64. Bioactives are added at col. 5, lines 11-27. While fibrin is the preferred gel material, other natural polymers are listed at col. lines 32-39. Synthetic polymers are included at col. 10 line 40 in the form of copolymers, and in col. 11, lines 33-35 as "recombinant material". It is noted that applicant claims a composition but includes method steps such as solvating and addition of pressure. These are

considered intended steps and are do not lend patentable weight. Further, if applicant is claiming a product by process, the claims should be reworded as such. Even so, the end product would have to be distinguished by comparative data from the end product as set out by Delmotte. The instant claims are anticipated by Delmotte.

Claims 1-5 and 9, 10 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 98/35653 (WO'653).

WO'563 sets out a collagen gel produced by the addition of water to collagen (see (Abstract)). Bioactives are listed at page 2, lines 31-35. As above the method steps do not differentiate from the gel as disclosed by WO'563. The instant claims are anticipated.

Claim Rejections - 35 USC § 103

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delmotte (US Patent No. 7,135, 027).

Delmotte disclose mixing fibrin (a natural polymer) with water under pressure of a syringe at col. 3, lines 11-12. Filler is added at col. 3, lin 62. Bioactives are also included at col. 6, lines 60-67. Synthetic polymers are incorporated by reference at col. 6, line 28 through US Patent No, 6,066,325 (see col. 7, lines 19-24). Those of ordinary skill would have therefore expected similar therapeutic characteristics from the instantly claimed gel given the gel as taught by Delmotte. There are no unusual and/or unexpected results which would rebut *prima facie* obviousness. As such, the instantly claimed gel composition would have been obvious to one of ordinary skill at the time of invention given the teachings of Delmotte.

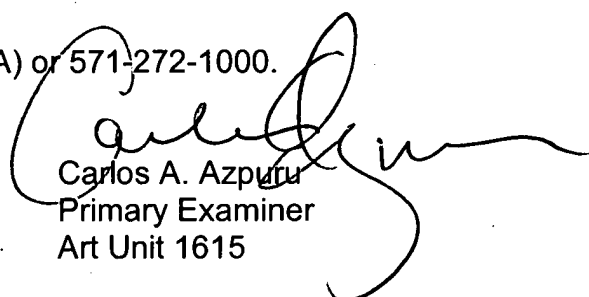
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru
Primary Examiner
Art Unit 1615

caz